DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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WARNING LETTER

WL-CIN-8758-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 27, 2001

Terry R. Renner, President
F.W. Renner & Sons, Inc.
1866 Sherrick Dr. SE
Canton, OH 44701

Dear Mr. Renner:

On 6/19/2001 and 6/22/2001 an FDA investigator conducted and inspection of your rendering plant at 1866 Sherrick Dr. Se, Canton, OH. The inspection revealed significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

The inspection found your firm failed to label meat & bone meal that contains, or may contain, prohibited materials with the required cautionary statement **"Do not feed to Cattle or Other Ruminants"**. We suggest this statement be distinguished by different type size or color or other means of highlighting the statement so it is easily noticed by the purchaser.

The deviations from the BSE regulations, as noted above, cause products being manufactured and distributed by your facility to be misbranded within the meaning of Section 403(f) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation. You should take prompt action to correct these violations, and you should establish a system whereby violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days after you receive this letter of the steps you have taken to bring your firm into compliance with the law. Specifically, your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the

delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Stephen J. Rabe, Compliance Officer at the address listed above.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District

Attachment: Small Entity Compliance Guide